

**Translation**

**PATENT COOPERATION TREATY**

PCT/JP2003/016397



**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

|  |   |  |
|--|---|--|
| Applicant's or agent's file reference<br>FP0099  | FOR FURTHER ACTION<br>See Form PCT/IPBA/416                                 |  |
| International application No.<br>PCT/JP2003/016397   | International filing date (day/month/year)<br>19 December 2003 (19.12.2003) | Priority date (day/month/year)<br>20 October 2003 (20.10.2003) |
| International Patent Classification (IPC) or national classification and IPC<br>C12M 3/00, 1/36, C12N 5/06, G01N 33/48 |   |  |
| Applicant<br>JMS CO., LTD.   |   |  |

|  |  |
|--|--|
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>8</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> |  |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>  |  |

|   |  |
|---|--|
| Date of submission of the demand<br>07 June 2004 (07.06.2004) | Date of completion of this report<br>01 December 2004 (01.12.2004) |
| Name and mailing address of the IPEA/JP                       | Authorized officer   |
| Facsimile No.   | Telephone No.  |

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International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the claims:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the drawings:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 5, 19, 44

because:

☒ the said international application, or the said claims Nos. 5, 19, 44  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 5, 19, 44

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the  
Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with  
the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ see Supplemental Box for further details.

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III. 1.

The inventions set forth in claims 5, 19 and 44 pertain to "a human tissue regeneration method...transporting stored cells into a living body" and as such, are considered to be equivalent to treatment (method) of the human body by therapy.

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees the applicant has:
- ☐ restricted the claims:
  - ☒ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☐ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
  - ☒ not complied with for the following reasons:  
SEE SUPPLEMENTAL SHEET

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-4, 6-18, 20-43

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: IV. 3.

The inventions set forth in claims 1-28 and 34-44 are groups of inventions related to a cell handling device having a simple structure, capable of satisfactorily storing cells while preventing the cells from becoming contaminated, and capable of easily injecting the cells into the living body by performing a treatment for releasing the cells from a container in a cell transplantation method, and a human tissue regeneration method using said device.

Meanwhile, the inventions set forth in claims 29-33 are a group of inventions related to a scaffold for breeding- and differentiation-inducing cells to greatly simplify the cell culturing operation.

Since both of these groups of inventions are considered to relate to different subject matter, these groups of inventions are not considered to be a group of inventions so linked as to form a single general inventive concept.

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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

|                               |        |                       |     |
|-------------------------------|--------|-----------------------|-----|
| Novelty (N)                   | Claims | 3, 7-18, 20-28, 34-43 | YES |
|                               | Claims | 1, 2, 4, 6, 29-33     | NO  |
| Inventive step (IS)           | Claims | 7-18, 20-28, 37-43    | YES |
|                               | Claims | 1-4, 6, 29-36         | NO  |
| Industrial applicability (IA) | Claims | 1-4, 6-18, 20-43      | YES |
|                               | Claims |                       | NO  |

### 2. Citations and explanations

Document 1: JP 06-13499 U (Sekisui Chemical Co., Ltd.),  
22 February 1994

Document 2: JP 06-98756 A (Nissho Corp.), 12 April 1994

Document 3: EP 489332 A1 (Boehringer Ingelheim KG.), 10  
June 1992

Document 4: JP 63-49070 A (Shimadzu Corp.), 1 March 1988

1. The inventions set forth in claims 1, 2, 4, 6, and 29-33 lack novelty and do not involve an inventive step in the light of documents 1-3 cited in the international search report.

(1) The inventions set forth in claims 1, 2, 4 and 6

Documents 1 and 2 disclose cell-handling devices capable of storing a cell-containing substance in a liquid form in a liquid-tight manner, wherein a gas-permeable region (formed using a gas-permeable resin) is provided at a part in contact with the cells and the capacity for storing the cells can be altered.

Therefore, the inventions set forth in claims 1, 2, 4, and 6 are essentially the same as the inventions disclosed in documents 1 and 2.

(2) The inventions set forth in claims 29-33

Document 3 discloses a microporous cell scaffold containing a vasicular material having a substance that promotes cell adherence and indicates that the diameter of the scaffold particles is between 20-300 $\mu$ m.

Therefore, the inventions set forth in claims 29-33 are essentially the same as that set forth in document 3.

2. The inventions set forth in claims 3 and 34-36 do not involve an inventive step in the light of documents 1-3 cited in the international search report.

In general, a person skilled in the art is capable of determining the (gas permeable) state of the gas exchange site suitably so that cells can be cultured/maintained appropriately in a device such as a cell-handling apparatus.

Consequently, it would be easy for a person skilled in the art to suitably determine the gas permeability in the inventions disclosed in documents 1-3 in such a manner that the cells are cultured/maintained. Even if specific numerical delimitations were given with regards to gas permeability, there appears to be no objective effect that would be considered unexpected arising from such delimitations. This being the case, it would not be difficult to apply specific delimitations.

3. The inventions set forth in claims 7-18, 20-28 and 37-43 are not disclosed in documents 1-4 cited in the international search report and are therefore, novel and involve an inventive step.